February 2013

Section-by-Section Summary: Delivering Antimicrobial Transparency in Animals (DATA) Act

Committee on Energy and Commerce

Minority Staff

SECTION 1. SHORT TITLE.

Section 1 provides the short title of the Act, the "Delivering Antimicrobial Transparency in Animals Act of 2013."

SECTION 2. FINDINGS.

Section 2 notes that a large proportion of antimicrobials sold in the United States are sold for use in food animals and describes the need for improved information about the use of these drugs in food animals.

SECTION 3. PURPOSE.

Section 3 sets forth the purpose of the DATA Act, which is to provide the FDA and the public with better information on the use of antimicrobial drugs in food animals in order to enable public health officials and scientists to better understand and interpret trends and variations in antimicrobial resistance, to improve the understanding of the relationship between animal uses of these drugs and antimicrobial resistance in animals and humans, and to identify interventions to prevent and control resistance.

SECTION 4. ENHANCED REPORTING REQUIREMENTS.

Section 4 amends Section 512(l) of the FFDCA to require drug sponsors to include in their annual FDA reports the dosage form and the known or estimated amounts of the antimicrobial ingredients in new animal drugs sold or distributed for use in each food-producing animal species for which the new animal drug is approved.

Section 4 further amends Section 512(l) of the FFDCA to require live poultry dealers, swine contractors, and feed lot operators who control at least $10,000,000 worth of live animals per year to submit annual reports to FDA on the antimicrobials used in their animal feed. For antimicrobials in feed under a Veterinary Feed Directive, the reports would be required to include information on quantities, dosages, and duration of time that the feed may have been provided to the animals.

Section 4 amends Section 512(l) of the FFDCA to improve the timing and quality of the summary information that FDA is required to make public. For example, FDA will be required to report data on the percentage of antimicrobials sold for growth promotion/feed efficiency, disease prevention, disease control, and disease treatment. Additionally, FDA will be required to provide the quantity of drugs sold or distributed state-by-state, as well as the quantity of drugs sold or distributed for each type of animal. For feed sold pursuant to a Veterinary Feed Directive, FDA must provide data on the indication for which the feed was sold or distributed, the quantities of feed sold or distributed for each such indication, the number of individual animals to which the feed was intended to be given, and the dosage and length of time for which such feed was intended to be given.

SECTION 5. ENHANCED COLLABORATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE DEPARTMENT OF AGRICULTURE.

Section 5 requires the Secretary of Health and Human Services to coordinate with the Secretary of Agriculture to improve the collection of data on the use of antimicrobial drugs in or on food producing animals.

SECTION 6. ACTION BY GOVERNMENT ACCOUNTABILITY OFFICE.

Section 6 requires the Secretary of Health and Human Services to publish, no later than 180 days after enactment of the DATA Act, a final guidance entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209."

Section 6 further requires GAO to study and publish a report to evaluate the voluntary approach used by the FDA to eliminate injudicious use of antimicrobial drugs in food-producing animals and the effectiveness of FDA's antimicrobial resistance data collection activities.